

REMARKS/ARGUMENTS

The Finality of the Office Action Is Improper

The Office Action mailed January 21, 2010 has been made final. The Office Action indicates on page 5 that the Office Action was made final because “[a]pplicant’s amendment necessitated the new ground(s) of rejection presented in this Office action.” The Office Action fails, however, to indicate how Applicant’s amendment necessitated the new ground(s) of rejection.

Applicants respectfully submit that it was premature for the Examiner to make the instant Office Action final. The Examiner is respectfully reminded that M.P.E.P. § 706.07(a) provides that “[a] second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, *on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed.*” (emphasis added).

In the instant Office Action, the Examiner has rejected claims 1-5, 7, 8, 12-17 and 34 under 35 U.S.C. 103(a) as being unpatentable over Lewandowski *et al.* (U.S. Patent App. Pub No. 2002/0138873) in view of Ainley *et al.* (U.S. Patent No. 6,384,207). Lewandowski *et al.* was not of record¹ until the Examiner cited this patent publication in the instant Office Action. Therefore, the Office has not previously provided Applicants with an opportunity to address the cited teachings of this document.

¹ Lewandowski *et al.* (U.S. Patent App. Pub No. 2002/0138873) was not cited in by Applicants in an Information Disclosure Statement nor was this patent publication cited by the Office in a Notice of References Cited (PTO-892). The Examiner is respectfully reminded that pursuant to M.P.E.P. § 707.05(c), the Examiner should have provided the citation for Lewandowski *et al.* in a Notice of References Cited (Form PTO-892). Applicants note for the record that they did not receive a copy of any such Notice citing Lewandowski *et al.* with the Office Action mailed January 21, 2010 nor were they able to find one on July 14, 2010 in the online Patent Application Information Retrieval record for the instant application.

Furthermore, the Examiner should have reasonably expected that Applicant might amend claim 1 to incorporate certain limitations of a dependent claim 6, particularly in view of the Examiner's statement in the prior Office Action that:

Although the combined teachings [of Lough *et al.* and Ainley *et al.*] do not teach an RNA replicon being a tobamovirus, the claims 6-8 reads on any RNA virus given broad interpretation of "said RNA replicon is based on a tobamovirus" (emphasis added).

Office Action mailed Apr. 30, 2009, p. 6.

Claim 6 (previously cancelled) reads as follows:

6. The system according to claim 1, wherein said RNA replicon (i) is based on, or contains components of, a tobamovirus.

Upon consideration of the Examiner's above-quoted statement, Applicants amended claim 1 in their last response to the Office to include a limitation from claim 6 but did not include the alternative limitation from claim 6, "based on a tobamovirus," in the interest of expediting prosecution of the instant application. Claim 1 as amended in Applicants' prior response recites, "said RNA replicon containing components of a tobamovirus". In view of the fact that claim 1 was amended to incorporate a limitation from dependent claim 6 and in further view of the above-quoted statement in the prior Office Action, Applicants submit that *claim 1 was amended to include limitations which the Examiner should reasonably have expected to be claimed by Applicants.*

In summary, the finality of the instant Office Action is premature because:

- (i) the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over **Lewandowski *et al.*** in view of Ainley *et al.* is based on a document (*i.e.*, Lewandowski *et al.*) that **was not of record**; and

- (ii) claim 1 was **amended to include limitations which should reasonably have been expected to be claimed** by Applicants.

In view of the above remarks, Applicants respectfully request that Examiner either withdraw the finality of the instant Office Action and issue a new, non-final Office Action so that Applicant has a proper opportunity to address the new ground for rejection of claims 1-5, 7, 8, 12-17 and 34 or issue a Notice of Allowance.

Request for Continued Examination

Applicants file concurrently herewith a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114. The instant paper is Applicants required submission under 37 C.F.R. § 1.114 to accompany the RCE.

Because Applicants earnestly believe that the Office Action mailed January 21, 2010 should not have been made final for the reasons stated above, Applicants respectfully request the Office to disregard the accompanying RCE and to refund the fees therefor, if the Office decides to withdraw the finality of the Office Action mailed January 21, 2010.

Status of the Claims

Prior to the claim amendments made hereinabove, claims 1-5, 7, 8, and 12-34 are pending, claims 1-5, 7, 8, 12-17, and 34 stand rejected, and claims 18-33 are withdrawn. Claims 6 and 9-11 were previously cancelled.

In the instant Amendment, Applicants have amended each of claims 1 and 25 without prejudice or disclaimer to recite in part (i), a DNA precursor of an RNA replicon, said RNA replicon being derived from a plus-sense single stranded RNA virus and comprising at least one sequence of interest, said DNA precursor of said RNA replicon containing in a replicase open reading frame (ORF) or in a movement protein ORF of said RNA replicon, one or more introns

near or within A/U rich localities of said sequences derived from said RNA virus. Support for this amendment to the claims can be found in original claim 1 and in the specification, particularly from beginning at the last two lines on page 24 to the end of the first paragraph on page 27.

Applicants have reinstated previously cancelled claims 6 and 9-11 as "new" claims 35-38, respectively. Support for the new claims can be found in original claims 6 and 9-11 and throughout the specification.

As set forth hereinabove, Applicants have cancelled claims 30-33 without prejudice or disclaimer for being directed to non-elected subject matter. Applicants expressly reserve the right to file one or more divisional applications or take such other measures deemed necessary to protect the subject matter encompassed by these cancelled claims.

No new matter has been added by way of the amendment of the claims or by the addition of the new claims.

Following the amendments made hereinabove, claims 1-5, 7, 8, 12-29, and 34-38 are pending. Claims 1-5, 7, 8, 12-17, and 34-38 are under examination. Claims 18-29 are withdrawn.

Reexamination and reconsideration of the application as amended are respectfully requested in view of the following remarks.

The Rejection of the Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-5, 7, 8, 12-17, and 34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lewandowski *et al.* (U.S. Patent App. Pub No. 2002/0138873) in view of Ainley *et al.* (U.S. Patent No. 6,384,207). Claim 1 has been amended. New claims 35-38 have been added.

The Examiner alleges that the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of

evidence to the contrary. This allegation is not credible because the Examiner has clearly misunderstood the subject matter encompassed by claim 1 and its dependent claim as is evidenced by the Examiner's characterization of the subject matter encompassed by claim 1 and its dependent claims 2-8 and 12-16 in the Office Action which provides:

Claims of 1-8² and 12-16 are drawn to a system for replicating and expressing a sequence of interest in a plant comprising i) ***a DNA precursor of an RNA replicon derived from a plus-sense single stranded RNA virus comprising at least one sequence of interest and one or more intron***; and ii) a DNA precursor of a helper replicon that is incapable of systemic movement in a plant both in the presence and in the absence of said RNA replicon and that is capable of expressing in a plant one or more protein necessary for systemic movement of said RNA replicon; whereby said RNA replicon is capable of replicating and expressing said sequence of interest in a plant but unable to move systemically in a plant in the absence of said one or more proteins expressed by said helper replicon; or wherein that said helper replicon is incapable of systemic movement in a plant is due to the absence of a functional origin of viral particle assembly; or wherein said helper replicon is capable of expressing in a plant a coat protein or a movement protein necessary for said systemic movement of said RNA replicon; or wherein said RNA replicon cannot express a movement protein necessary for said systemic movement of said RNA replicon; or wherein said plant is a tobacco plant; or wherein said replicon lacks a coat protein and said sequence of interest is larger than 1 kb.

Office Action mailed Jan. 21, 2010, p. 3 (emphasis added). In particular, the Examiner misconstrued claims 1-8 and 12-16 because neither claim 1 nor any of dependent claims 2-8 and 12-16 recites that the RNA replicon is "***derived from a plus-sense single stranded RNA virus***" as alleged in the Office Action. *Id.* (emphasis added).

In response to the prior Office Action (mailed April 30, 2009), Applicants amended claim 1 to delete the recitation "being derived from a plus-sense single stranded RNA virus " as shown below:

² Claim 6 was cancelled by Applicants in their Amendment filed Sept. 30, 2009 and thus, was not pending at the time the Office Action mailed January 21, 2010 issued.

1. (Currently amended) System for replicating or for replicating and expressing a sequence of interest in a plant, comprising:

- (i) a DNA precursor of an RNA replicon, said RNA replicon ~~containing components of a tobamovirus being derived from a plus-sense single-stranded RNA virus~~ and comprising at least one sequence of interest, said DNA precursor of said RNA replicon containing one or more introns; and
- (ii) a DNA precursor of a helper replicon, wherein said helper replicon is
 - (a) incapable of systemic movement in a plant both in the presence and in the absence of said RNA replicon (i) and
 - (b) capable of expressing in a plant one or more proteins necessary for systemic movement of said RNA replicon (i),

whereby said RNA replicon (i) is capable of replicating or of replicating and expressing said sequence of interest in a plant, but unable to move systemically in a plant in the absence of said one or more proteins expressed by said helper replicon (ii).

Amendment filed Sept. 30, 2009, p. 5.

Curiously, the Examiner omitted claims 17 and 34 altogether from his characterization of the subject matter of the claims on page 3 of the instant Office Action. While pending claim 17 is a dependent claim that ultimately depends from claim 1, pending claim 34 is an independent claim drawn to a system for replicating or for replicating and expressing a sequence of interest in a plant and is not identical to pending claim 1. At the very least, the Examiner is required to provide a reasoned basis for rejecting claim 34 under 35 U.S.C. § 103(a), but he has failed to do this and as a result, has not afforded Applicants with a proper opportunity to respond to the rejection of claim 34. Accordingly, Applicants respectfully invite the Examiner to state with particularity in the next Office Action the basis for rejecting claim 34 under 35 U.S.C. § 103(a)

as being unpatentable over Lewandowski *et al.* in view of Ainley *et al.* or to withdraw this rejection and allow this claim.

In view of the above evidence that the Examiner has misconstrued the claims and has failed to provide a reasoned statement for rejecting claim 34 under 35 U.S.C. § 103(a), Applicants respectfully submit that the Examiner has failed to state a *prima facie* case of obviousness against claims 1-5, 7, 8, 12-17, and 34 based on the combination of Lewandowski *et al.* and Ainley *et al.*

Notwithstanding Applicants' position that the Examiner has misunderstood the scope of the claims that were pending at the time of the instant Office Action, Applicants have amended claim 1 and provide below the following additional comments in the interest of expediting examination of the instant application.

The inventors have surprisingly found that introduction of one or more introns into A/U-rich regions of the replicase ORF or the movement protein ORF of a DNA precursor of an RNA replicon, as defined in amended claim 1 leads to an increased frequency of replicon formation in the cytoplasm, thereby increasing the expression level of a sequence to be expressed from a replicon. The Examples in Applicants' specification demonstrate the effect of the present invention.

RNA viruses typically replicate in the cytoplasm of cells, for which RNA viruses are optimized by evolution. If RNA replicons are provided to cells or plants via DNA precursors, transcription of the DNA precursors has to take place inside cell nuclei, where transcripts are exposed to the nuclear RNA processing machinery. However, RNA viruses are not optimized to the plant nuclear RNA machinery. It is a contribution of the inventors to have recognized the causal connection between low frequencies of RNA replicon formation in cells when transcribed from DNA precursors and the lack of optimization of RNA replicons to the plant nuclear RNA processing machinery. It is a further contribution of the inventors to have identified specific areas in sequences derived from RNA viruses, namely A/U-rich localities, where the effect of intron insertion is particularly high. This aspect of the invention is described in detail starting

from page 24, bottom to page 27, middle of the specification. In addition, the Examples in Applicants' specification contain experimental data in support of the invention.

In contrast to the view stated in the Office Action, a person having ordinary skill in the art would not find that the combination of Lewandowski *et al.* and Ainley *et al.* renders obvious Applicants' claimed invention for the following reasons. First, Lewandowski *et al.* is unrelated to the subject-matter of new claim 1 because it does not relate to the problem of improving the frequency of RNA replicon formation in plant cells when provided to plant cells from DNA precursors or the RNA replicons. Further, Lewandowski *et al.* contains no hint to the solution according to claim 1. Second, at the time of Applicants' invention, Ainley *et al.* would not have been considered by a person having ordinary skill in the art who was trying to improve the efficiency of RNA viral replicon formation from DNA precursors thereof, since Ainley *et al.* does not relate to RNA replicons. The prior art is not even aware that the frequency of RNA replicon formation from transformed DNA precursors can be improved in plant cells. Notably, Ainley *et al.* is silent on the introduction of introns into A/U-rich localities of sequences derived from an RNA virus of a DNA precursor of an RNA replicon. Thus, the cited combination of documents fails to render obvious the invention as presently claimed.

In view of the amendments and remarks, it is submitted that the rejection of the claims under 35 U.S.C. § 103(a) should be withdrawn and not applied to the newly submitted claims.

Request for Rejoinder of the Withdrawn Claims

In the event that the Examiner determines the amendments made herein place all of the claims under examination in an allowable form, Applicants respectfully request that the Examiner rejoin the withdrawn claims and examine and then allow these claims. As set forth above, Applicants have amended withdrawn claim 25 in a manner that is identical to the amendment of claim 1.

Appl. No.: 10/586,998
Amdt. dated July 20, 2010
Reply to Office Action of January 21, 2010

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. § 103(a) are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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